K083614

PG. 1 OF 3

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11.3 A "510(K) SUMMARY"

a) Sponsor/manufacturing Information

Sponsor's name:	EDAP TMS France S.A.
Contact person:	Mr Bruno PAGES, Quality & Regulatory Affairs Director
Address of sponsor:	4 rue du Dauphiné 69120 Vaulx-en-Velin France
Telephone number :	(011) 33 4 72 15 31 50
Facsimile number :	(011) 33 4 72 15 31 51
Manufacturer name:	EDAP TMS France S.A.
Contact person:	Mr Bruno PAGES, Quality & Regulatory Affairs Director
Address of manufacturer:	4, rue du Dauphiné 69120 Vaulx-en-Velin France
Telephone number :	(011) 33 4 72 15 31 50
Facsimile number :	(011) 33 4 72 15 31 51

b) Proposed Device

Common name of the Medical Device	Extracorporeal Shock Wave Lithotripter and Accessories
Trade / Proprietary Name	SONOLITH® I-SYS Module
CFR Number	21 CFR 876.5990 (Extracorporeal shock wave lithotripter)
Regulatory Class	Class II (Special Controls)
Product Code	78 LNS
Common name of the Medical Device	Endo-Urology Table and Accessories
Trade / Proprietary Name	SONOLITH® I-SYS Table
CFR Number	21 CFR 876.4890 (Urological table and accessories)
Regulatory Class	Class II (Special Controls)
Product Code	MMZ

c) Predicate Device(s)

Device # 1 - EDAP TMS France S.A.**SONOLITH® Praktis**, marketed via 510(k) n° K003529.
Device # 2 - Dornier Medical Systems, Inc. **DoLi S,** marketed via 510(k) n° K011873

d) Device Description

The SONOLITH® I-SYS medical device is a lithotripter of ESWL type (Extracorporeal Shock Wave Lithotripsy). The physical principle consists in delivering pulsed pressure waves which are focalized on the stone to be treated, at fixed frequency or patient synchronized frequency.

The SONOLITH® I-SYS ESWL generator Diatron IV uses a patented electrode including a reservoir with a highly conductive solution. This electrode type is the same for the previous generator Diatron III used in clinics and hospitals for several years.

A silicone membrane mounted on the top of the generator ensures the acoustical coupling between the generator and the patient's skin. Moreover, the generator benefits from a real time pressure servo control device.

The shock wave generation consists of emitting an electrical discharge at the first focus (F1) of the truncated ellipsoid. The shock wave generated is bent back by the ellipsoid's inner wall to be precisely concentrated at the second focus (F2) located at 264.62 mm above F1. The highly conductive liquid incorporated into the electrode guarantees a very high stability of the electrical arc at F1 ensuring very low dispersion at F2.

An X-ray subsystem is fully integrated as standard in the whole versions of the main treatment module (MIS) of the Sonolith® I-Sys system. Each X-ray subsystem is manufactured and controlled before integration in the lithotripsy platform. Two size of image intensifier are available,one with a 23cm (9") Image Intensifier and the other one with a 31cm (12") Image Intensifier.

On the Sonolith® I-Sys range, the only authorized X-ray modes of operation are:

- Continuous Fluoroscopy,
- Pulsed Fluoroscopy,
- Snapshot

The Ultrasound sub-system can be used with the Sonolith® I-sys in two versions. The first one is an external U/S scanner mounted on a trolley (including electronic rack, screen, operator interfaces). The second one, using the same electronic system, is integrated in the main treatment module of the Sonolith® I-sys. The U/S imaging allows the operator to follow in real time and non stop the localization of the calculus, because the ultrasound diagnosis is considered harmless for the patient.

The patient's support Table (TIS) is designed to allow 4 different working modes:

- Used during a Lithotripsy procedure with a treatment module like the Sonolith® I-SYS MIS,
- Used during a Lithotripsy procedure with a treatment module like the Sonolith® Praktis.
- 2 modes for endo-urology uses with the patient right or left oriented.

In any configuration, the local user interfaces can be a remote control keypad (hand button box) or a footswitch pedal. Both are controlling all the movements of the table.

ANNEX 17

Reply 17

a) Intended Use

The Sonolith I sys is intended to fragment stones in the kidney (renal pelvis and renal calyces) and the ureter (upper, middle and lower ureter)

The Endourology table I-sys table is intended for urological diagnostics, endourological interventions (e.g. TURP) extracorporeal lithotripsy in conjunction with the diagnostic and therapeutic module of the platform.

b) Technological Characteristics

Shock Wave Characteristics are presented in the following table for minimum, typical and maximum shock wave generator output settings. The hydrophone used to conduct the testing complies with FDA's 1991 SWL Guidance Document. The Shock Wave Characteristics, however, were measured using IEC 61846.

The following table shows the synthesis of the acoustics' measurements realized with the ellipsoid Diatron IV and an electrode of type TMS 220830B.

Acoustic parameter	DIATRON IV
	Min / Typical / Max
Peak-positive acoustic pressure (MPa)	111 / 126 / 129 (1)
Peak-negative acoustic pressure (MPa)	< 10
Rise time (ns)	44 / 47 / 48
Compressional pulse duration (ns)	138 / 174 / 188
Maximum focal width - X (mm)	2.2 / 3.1 / 3.2
Orthogonal focal width - Y (mm)	1.5 / 2.3 / 2.6
Focal extent - Z (mm)	14.2 / 21.7 / 22.4
Focal Volume (mm^3)	24.9 / 79.4 / 103.5 (2)
Distance Focus – target location (mm)	8 / 11 / 12 (3)
Derived focal acoustic pulse energy (mJ)	1.8 / 6.7 / 8.3
Derived acoustic pulse energy at R=3 mm (mJ)	8.6 / 21 / 23.6
Derived acoustic pulse energy at R=6 mm (mJ)	16.3 / 43 / 52

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 7 2009

EDAP Technomed Medical Systems France, S.A.
% Ms. Lynette Howard
Consultant
Lyle HOWARD Corporation
106 East 5th Avenue
MOUNT DORA FL 32757

Re: K083614
Trade/Device Name: SONOLITH® I-SYS Treatment Module and SONOLITH® I-SYS Table
Regulation Number: 21 CFR 876.5990
Regulation Name: Extracorporeal shock wave lithotripter
Regulatory Class: II
Product Code: LNS
Dated: July 13, 2009
Received: July 15, 2009

Dear Ms. Howard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K083614

ANNEX 16

Indications for Use

510(k) Number (if known) : K083614

Device Name : **SONOLITH® I-SYS Treatment module and SONOLITH® I-SYS TABLE**

Indications for Use :

The Sonolith I sys is intended to fragment stones in the kidney (renal pelvis and renal calyces) and the ureter (upper, middle and lower ureter)

The Endourology table I-sys table is intended for urological diagnostics, endourological interventions (e.g. TURP) extracorporeal lithotripsy in conjunction with the diagnostic and therapeutic module of the platform.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K083614